FDA 510(k) Premarket Notification

K002352 JMS A.V. FISTULA NEEDLE SET ACCORDION TYPE

CLEARED

Sep 6, 2001
400 days to decision

K002352 · Product code: **FIE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k002352/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Fistula (FIE)
Date received	Aug 2, 2000
Decision date	Sep 6, 2001
Days to decision	400 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Jms Co., Ltd.**
Location	Hiroshima, JP
Contact	KEISUKE URATOMI
510(k) history	24 submissions · 24 cleared · 1985-2001